

A review of medical device regulations in India, comparison with European Union and way-ahead

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Abstract

Indian healthcare sector is a fast-growing industry which is expected to reach \$280 billion by 2025. Medical devices market in India is one of the top 20 medical device markets in the world. It is currently valued at \$5.2 billion and is expected to reach \$50 billion by 2025. However, India does not manufacture many devices indigenously and still imports approximately 70% of its medical devices. Manufacturing and monitoring of medical devices are highly regulated activities. In India, there were no specific medical device regulations and devices were regulated under the Drugs and Cosmetics Act, 1940. To fulfill this gap, Central Drug Standard Control Organization released Indian Medical Device Rules, 2017, which are the new regulations for medical devices in India. Keeping pace with the requirements, these were amended as Medical Devices (Amendment) Rules, 2020, which has come into force in April 2020. These rules cover various aspects of device related regulations, including classification, registration, manufacturing and import, labeling, sales, and postmarket requirements, etc. The rules are a positive step and encompass most of the European Union (EU) approval process, which mandates that the devices are safe and performs its intended function. However, with rapid advancements in medical device technology, much is desired in clarity and revamping of the current regulatory system to harmonize standards to be in-line with advanced regulations like EU.

Keywords: *In vitro* diagnostics, Indian regulations, medical device regulations, medical device rules 2017, medical devices

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Received: 10-07-20, **Accepted:** 15-02-21, **Published:** 12-07-21.

INTRODUCTION

Healthcare sector in India has undergone significant upgrades in the 21st century. Over the years, India has attained a 10% growth rate in this sector and by 2025 it is expected to reach \$280 billion.^[1] In 2016, percapita spending on healthcare in India was \$75 which was negligible in comparison to that of the United States, European Union (EU), China, and the Global average which was \$9403, \$3613, \$420, and \$1061, respectively.^[2]

Today Indian healthcare market size is \$128 billion and is expected to grow at 12% for next four years.^[3]

Medical devices have emerged as a key aspect in the healthcare sector of any developing healthcare sensitive nation. These are used for various functions in the field of healthcare, as but not limited to, screening and diagnosis, treatment/care, restoration, and monitoring. The medical device market in India is one of the top 20 medical device markets globally.^[4] It is growing at a fast pace of 15% annual

Access this article online	
Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/picr.PICR_222_20

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How to cite this article: Manu M, Anand G. A review of medical device regulations in India, comparison with European Union and way-ahead. *Perspect Clin Res* 2022;13:3-11.

growth rate and is expected to touch \$50 billion by 2025.^[1,4] The devices distributed in various segments differ in terms of market share in India. Largest segment is of the medical instruments and appliances (34%), followed by diagnostic imaging devices (31%), consumables and implants (19%), and patient aids and others (16%).^[1]

Approximately 70% of medical devices in India are imported.^[4] This gap in import vs. manufacturing provides a big opportunity to medical device manufacturers to fulfill this gap by indigenous manufacture and sales. Currently, the medical device development process is very complex and is time-consuming. Its approval is one of the most structured processes, which is highly regulated and governed by Indian Medical Device Rules (IMDR) 2017^[5] and Medical Devices (Amendment) Rules, 2020.^[6] These rules cover various aspects of device-related regulations, including classification, registration, manufacturing and import, labeling, sales, and post-market requirements, etc. The process of device development from conceptualization to post-marketing surveillance (PMS) is explained in Figure 1.

The new EU Medical Device Regulations (MDR)^[7] and *in vitro* Diagnostic Regulation (IVDR),^[8] 2017 make notified bodies, competent authorities and the European Commission more responsible than ever before for the safety of medical devices, including *in vitro* Diagnostics. Now all the medical devices need to be reassessed for compliance and certification. In the EU, clinical evaluation is the foremost step for demonstrating and establishing the safety of medical devices. It is also an important instrument for longterm safety evaluation and continuous safety monitoring of the devices. The European Parliament and the Council of the EU recently (April 23, 2020) adopted a proposal to extend the transitional period of the MDR by 1 year (26 May 2021) while there is no delay in the IVDR implementation (applicable from 26 May 2022).^[9] The updated guidelines have many commonalities with the USFDA guidelines which are stringent with respect to approval process. While clinical evaluation requirements in India as per IMDR are limited to the development phase of only certain medical devices; though post-market requirements are there, they have their own limitations. As both guidelines were updated, were effective at nearly the same period, and are constantly adapting, a comparison is being made in this article.

NEW MEDICAL DEVICE RULES

As medical devices deal with the health and safety of the patients, their manufacturing is done in a strictly regulated environment, and they fulfill stringent regulatory

requirements and guidelines. While the drug regulations in India are well established for decades, a well-defined regulation for medical devices was missing for long. Nevertheless, the Indian regulatory regime for medical devices has recently been very active.^[10] Medical Devices and Diagnostics Division of Central Drug Standard Control Organisation (CDSCO) has developed structured regulations for medical devices, IMDR which was released in January 2017 and came into force from January 2018.^[5] IMDR was amended in February 2020 as “Medical Devices (Amendment) Rules, 2020” and came into force in April 2020. The 2020 amendment was released with an addition of “registration of certain medical devices”.^[6] Though many of the medical devices still continue to be controlled as drugs under the Drugs and Cosmetics Act, 1940, the advent of the IMDR and other supporting guidelines has paved the way for India to move its first step towards enhanced patient safety with respect to medical devices. Future amendments of IMDR can focus on fulfilling the gaps that would have equated these regulations with that of MDR and IVDR of EU, which are the most recent international regulations for medical devices for device safety and performance. A roadmap of the development of the regulatory system for medical devices in India is presented in Figure 2.

As per the IMDR, rules are applicable to both medical devices and IVDMDs that:

- Can be licensed for-import; manufacture for sale or for distribution; and sale, stock, exhibit or offer for sale
- May be manufactured for the purpose of clinical investigations, test, evaluation, examination, demonstration or training.

The IMDR talks about all the regulatory aspects of the medical devices, including regulations covering classification, grouping, essential principles, and product standards; governing bodies and authorities; registration; manufacture; import; labeling; clinical investigation or clinical performance evaluation; duties of officers and governing bodies; lab registration; sale of medical devices; parameters of classification; fees; notified body; grant of license; quality management system; post-approval changes; PMS, and exemptions [Figure 3].

DEVICE CLASSIFICATION

Based on intended use of the device, risk associated with the device and other parameters referred to in IMDR,^[5] the Central Licensing Authority (CLA) of India classifies Medical Devices and IVDMDs into four risk classes.

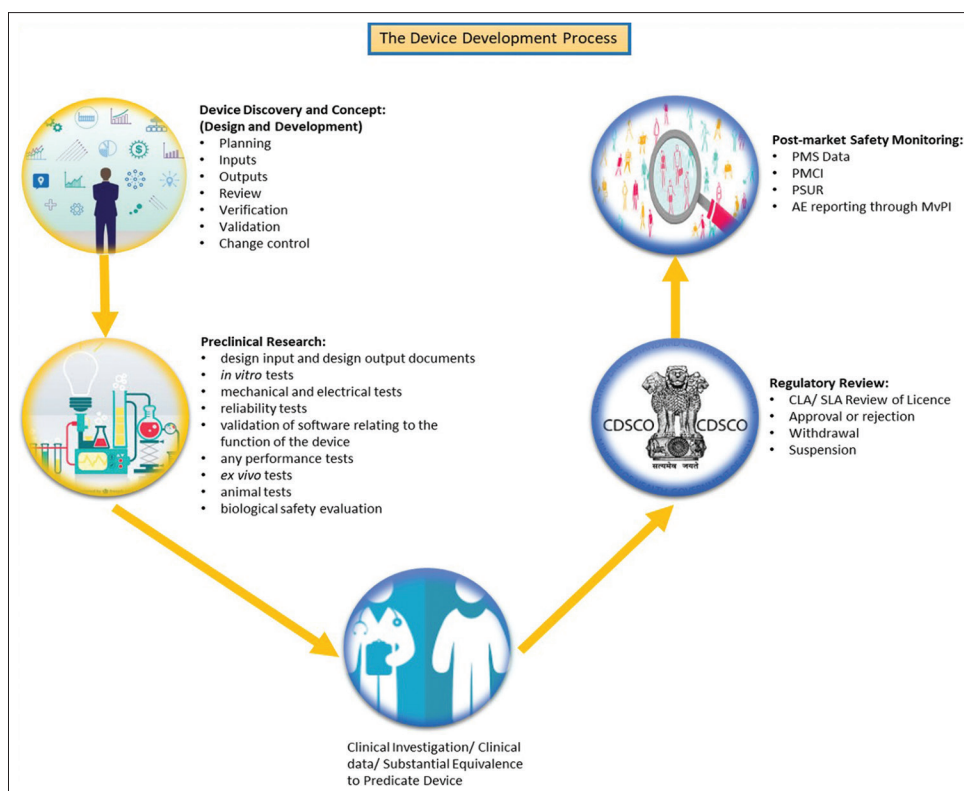


Figure 1: Medical device development and approval process. CLA: Central Licensing Authority; MvPI: Materiovigilance Program of India; PMCI: Post Marketing Clinical Investigation; PMS: Post Marketing Surveillance; PSUR: Periodic Safety Update Report; SLA: State Licensing Authority

- low risk-Class A
- Low moderate risk-Class B
- Moderate high risk-Class C
- High risk-Class D.

The classification of Medical Devices or IVDMDs is based on the following principles:

- Application of classification to be governed by intended purpose of the device or IVDMDs [Figure 4]
- Combination devices or accessories to be classified separately
- Software to be classified in the same class as of its associated device
- Calibrators used with a reagent to be have the same class as the IVDMD reagent
- Device with multiple specified uses to be classified per most critical use
- If several rules apply, stringent rules resulting in higher classification to be applied.

MANUFACTURING

For the manufacture of class A/B devices, license or loan license against the application is granted by the State Licensing Authority. While for manufacturing class C/D devices the license or loan license is granted by CLA.

These licenses remain valid in perpetuity, unless suspended or canceled, if the license retention fee is paid before completion of 5 years from the date of issue.

The small quantity of medical devices may be manufactured for clinical investigations, tests, evaluation, examination, demonstration, or training. This license is valid for 3 years.^[5]

CLINICAL INVESTIGATION OR CLINICAL PERFORMANCE EVALUATION

Similar to approval of drugs, a clinical investigation of an investigational medical device is required in or on human participants to assess its safety, performance, or effectiveness. For a new IVDMD, a clinical performance evaluation is required on specimens collected from human participants to assess its performance. Clinical investigation or clinical performance evaluation are performed based on the clinical investigation plan or clinical performance evaluation plan respectively, which are detailed documented protocols for their conduct [Figure 5].^[5] Furthermore, during this process, the rights, safety, and wellbeing of the subjects should be protected consistent with the ethical principles laid down in the Declaration of Helsinki.^[10]

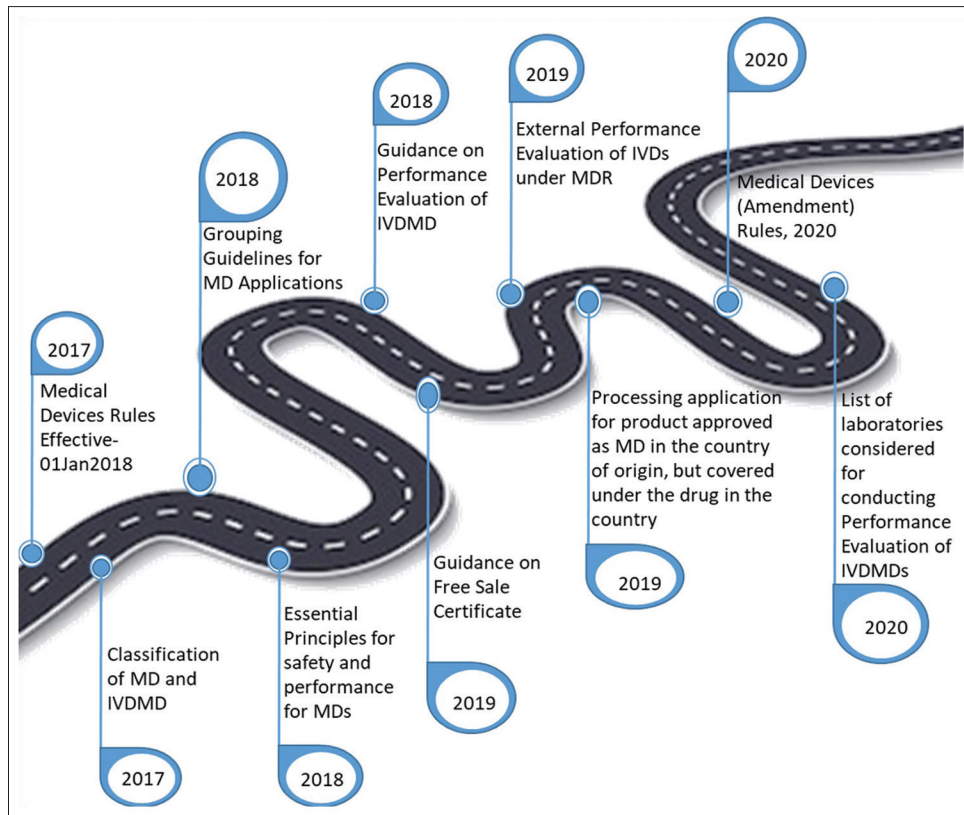


Figure 2: Roadmap of Indian regulations on medical devices. IVDMD: *In vitro* Diagnostic Medical Device; IVDs: *In vitro* Diagnostics; MD: Medical Device

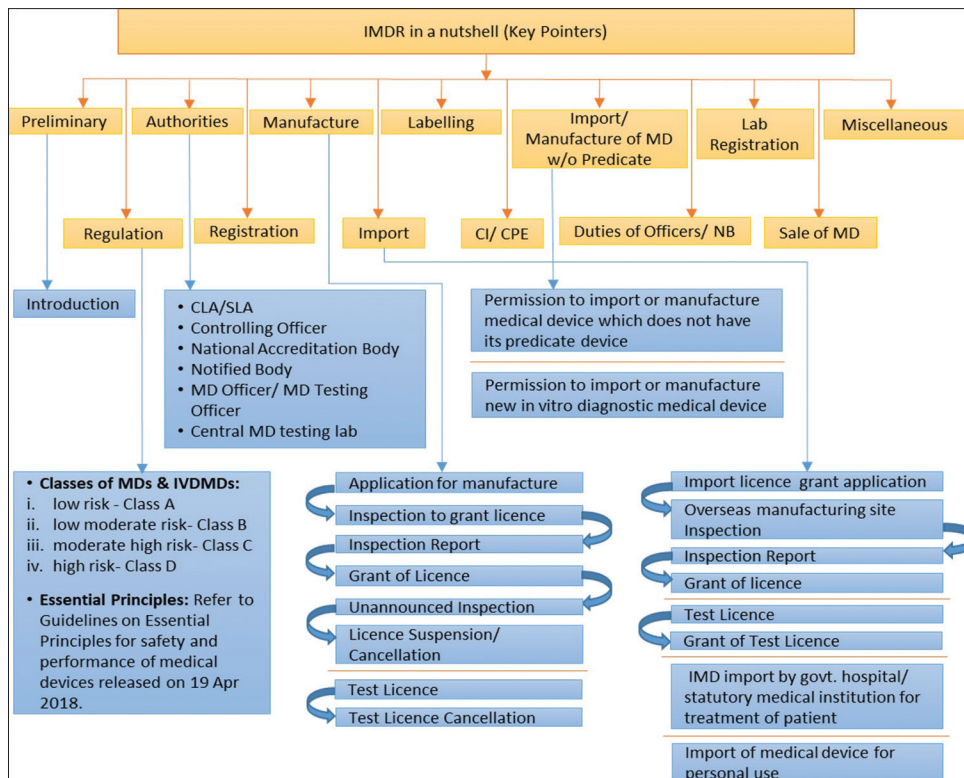


Figure 3: IMDR summary in a nutshell. CI: Clinical Investigation; CLA: Central Licensing Authority; CPE: Clinical Performance Evaluation; IMDR: Indian Medical Device Rules, 2017; IVDMD: *In vitro* Diagnostic Medical Devices; MD: Medical Device; NB: Notified Body; SLA: State Licensing Authority; w/o: without

Medical devices categorized under IMDR need to undergo only two-phase studies, i.e., pilot (exploratory study) and (pivotal study) clinical investigations, unlike four-phase studies required in Schedule Y. For a clinical investigation or clinical performance evaluation, a clinical investigation report or a clinical performance evaluation report, respectively, is required to be provided to the ethics committee, participating investigators, and to the CLA for a completed or prematurely terminated study.^[5]

In India, Clinical Investigation is required for all class B, C, and D medical devices if the device is an investigational medical device that does not have a predicate device and is manufactured in the country; or if it is a new IVDMD. However, Clinical investigation is not required to grant the import license, if the device is already marketed for at least 2 years in Australia, Canada, Japan, Europe or the United States and the respective CLAs are satisfied with the available clinical evidence. In such cases, CLA may require post-marketing investigation based on subject expert committee's review and recommendation.

For grant of import licence for medical devices from other countries, a clinical investigation is required to be conducted in India for class C/D devices to establish their safety and effectiveness; for class A/B devices, import licence can be

granted if the safety and performance have been established through published data or through clinical investigation in the country of origin, and a free sale certificate from the country of origin is furnished. Figure 5 briefs the major process steps required in clinical investigation or clinical performance evaluation and key conditions for permission to perform it.^[5]

VIGILANCE REPORTING/POST MARKETING SURVEILLANCE DATA

The medical device manufacturer has an obligation to make a vigilance report or a PMS data from medical devices that have been placed in the market. This report should contain reporting procedure, complaints received, and corrective and preventive action for that.^[5]

Manufacturers are required to conduct a post marketing clinical investigation (includes additional drug-device interaction, safety studies, investigation designed to support use under the approved indication, e.g. mortality or morbidity studies, etc.) for testing the safety and performance of an investigational medical device which does not have its predicate device.^[5]

To monitor the clinical safety, a PSUR for each medical device is required to:

<p>I. IVDMDs for detecting transmissible agents, etc.:</p> <p>A. IVDMDs for detecting the presence of, or exposure to, a transmissible agent that:</p> <ol style="list-style-type: none"> 1. is in blood*, to assess suitability of blood* for transfusion or transplantation 2. causes a life-threatening disease with a high risk of propagation <p>Assigned to class D</p> <p>B. IVDMD intended for use in:</p> <ol style="list-style-type: none"> 1. detecting a sexually transmitted agent 2. detecting an infectious agent with a risk of limited propagation in cerebrospinal fluid or blood 3. detecting an infectious agent where there is a significant risk that an erroneous result will cause death or severe disability 4. pre-natal screening of women to determine their immune status towards transmissible agents 5. determining infective disease status or immune status** 6. screening for disease stages, for the selection of patients for selective therapy and management, or in the diagnosis of cancer 7. human genetic testing 8. monitoring levels of medicinal products, substances or biological components** 9. management of patients suffering from a life-threatening infectious disease 10. screening for congenital disorders in the foetus <p>Assigned to class C</p>	<p>II. IVDMDs for blood grouping and tissue typing:</p> <p>A. to ensure the immunological compatibility of blood* for transfusion or transplantation</p> <p>Assigned to class C</p> <p>B. if it is intended to be used for blood grouping or tissue typing according to the ABO system, the Duffy system, the Kell system, the Kidd system, the rhesus system</p> <p>Assigned to class D</p> <p>III. IVDMDs for self-testing:</p> <p>A. if it is intended to be used for self-testing</p> <p>Assigned to class C</p> <p>B. if it is intended to be used to obtain:</p> <ol style="list-style-type: none"> 1. test results that are not for the determination of a medically-critical status 2. preliminary test results which require confirmation by appropriate laboratory tests <p>Assigned to class B</p> <p>* includes blood, blood component, blood derivative, cell, tissue or organ ** where there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient being tested</p>	<p>IV. IVDMDs for near-patient testing:</p> <p>A. if it is to be used for near-patient testing in a blood gas analysis or a blood glucose determination</p> <p>Assigned to class C</p> <p>V. IVDMDs used in <i>in vitro</i> diagnostic procedures:</p> <ol style="list-style-type: none"> 1. if it is a reagent or an article which possesses any specific characteristic that is intended by its product owner to make it suitable for an <i>in vitro</i> diagnostic procedure related to a specific examination 2. an instrument intended specifically to be used for an <i>in vitro</i> diagnostic procedure 3. a specimen receptacle <p>Assigned to class A</p> <p>VI. Other IVDMDs:</p> <ol style="list-style-type: none"> 1. if it is not any of the mentioned IVDMDs; or 2. It is a substance or device used for the assessment of the performance of an analytical procedure or a part thereof, without a quantitative or qualitative assigned value <p>Assigned to class B</p>
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Figure 4: Parameters for classification for *In vitro* diagnostic medical devices. IVDMDs: *In vitro* Diagnostic Medical Devices

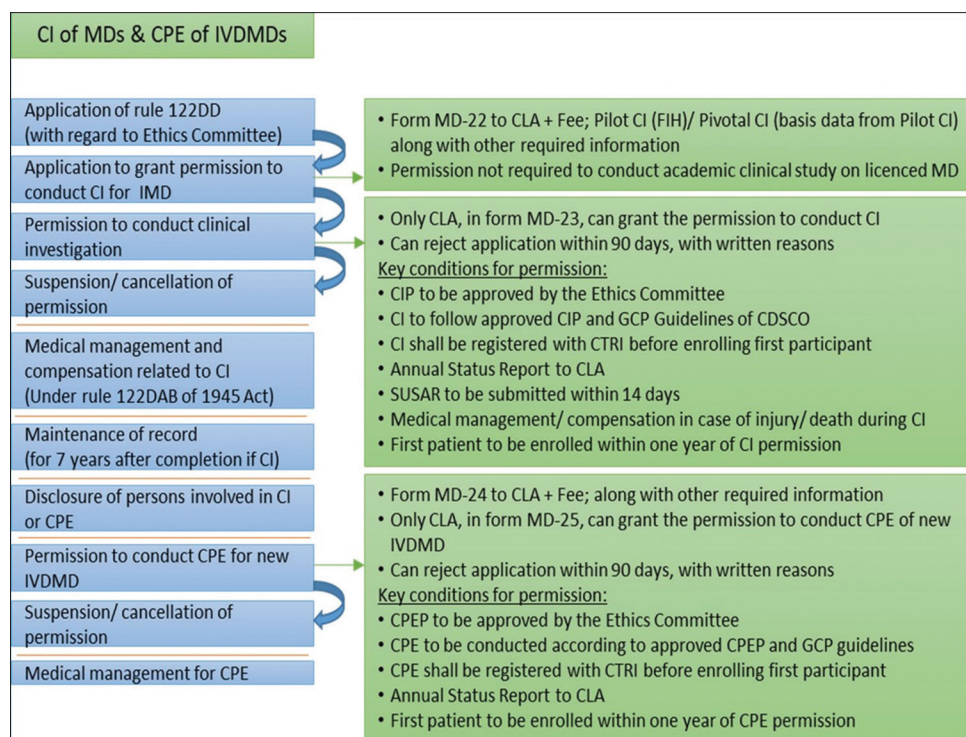


Figure 5: Clinical investigation of medical device and clinical performance evaluation process of new IVDMD. CDSCO: Central Drug Standard Control Organisation; CI: Clinical Investigation; CIP: Clinical Investigation Plan; CLA: Central Licensing Authority; CPE: Clinical Performance Evaluation; CPEP: Clinical Performance Evaluation Plan; FIH: First in Human; GCP: Good Clinical Practice; IVDMD: *In vitro* Diagnostic Medical Device; MD: Medical Device; SUSAR: Suspected Unexpected Serious Adverse Reaction

- Report all the relevant new information from appropriate sources
- Relate these data to patient exposure
- Summarise the market authorization status in different countries and any significant variations related to safety; and
- Indicate whether changes will be made to product information to optimize the use of the product.

The PSUR also captures any significant changes to the reference safety information within the reporting interval. Such changes include information relating to contraindications, warnings, precautions, adverse events (AE), and important findings from ongoing and completed clinical investigations and significant nonclinical findings.^[5]

For risk minimization and sustaining a better risk-benefit ratio, Indian Pharmacopoeia Commission runs Materiovigilance Program of India (MvPI) for the vigilance of medical devices. With continuous monitoring, it helps in assessing and detecting adverse effects of medical devices, malfunctions, etc. that can result in mortality and morbidity.^[11] Since the launch of this program, MvPI has played a vital role in keeping unsafe products at bay and

till date a total of 16 medical devices have been recalled from the Indian market.^[12]

COMPARISON BETWEEN IMDR AND EUROPEAN UNION MEDICAL DEVICE REGULATIONS/ EUROPEAN UNION *IN VITRO* DIAGNOSTIC REGULATION

The new EU guidelines are patient-centric and set stringent requirements for device performance and safety, before as well as after the device is placed in the market. The medical devices and IVDMDs in EU are governed by two separate guidelines, MDR and IVDR, respectively.^[7,8] The IMDR also encompasses many approval processes similar to that of the EU which mandate that the device performs its intended functions. It covers all the IVDMDs and only a set of medical devices that are not already regulated as drugs in the Drugs and Cosmetics Act, 1940.^[5]

A comparison of few key terminologies and processes during device development and approval steps, highlighting similarities and differences between India and EU has been given in the Table 1. These may act as a reference for future updates in IMDR guidelines and are discussed in Way Forward section.

Table 1: Terminology or processes comparison between India and European Union for medical devices/*In vitro* diagnostic medical devices

Country	India ^[5,6]	Europe ^[7]	Europe ^[8]
Process or terms/ guidelines	Medical device rules including IVDMDs	Medical device regulations	<i>In vitro</i> diagnostic regulations
Definition (summary)	Substances used for <i>in vitro</i> diagnosis and surgical devices, blood and blood component collection bag with or without anticoagulant, mechanical contraceptives, disinfectants and insecticides, and other notified devices	Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for helping in disease, injury or disability, replacement or modification of anatomy or for providing information by <i>in vitro</i> examination, without pharmacological, immunological or metabolic means	IVDMDs are medical devices which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, to be used <i>in vitro</i> for the examination of specimens to determine the safety and compatibility with potential recipients, to predict treatment response or reactions, or to define or monitoring therapeutic measures
Devices covered	As above and those devices that are not already regulated as drugs in the drugs and cosmetics act, 1940	As above	As above
Device classification (in increasing order of risk posed)*	Class A, B, C and D	Class I, IIa, IIb and III	Class A, B, C and D
Clinical evaluation	Design and development validation performed for the medical device. A requirement for import and/or manufacture of the medical device (with some exceptions for few countries as defined in the paper)	Analysis of the clinical safety and performance of the device. Done throughout the lifecycle of the medical device	NA
Performance evaluation	Design and development validation performed for the IVDMD. A requirement for import and/or manufacture of the IVDMD	NA	Analysis of the clinical safety and performance of the device. Done throughout the lifecycle of the IVDMD
Evaluation report	Clinical evaluation report for medical devices (but nothing specified in details); performance evaluation report for IVDMDs	Clinical evaluation report	Performance evaluation report
Clinical investigation report*	Clinical investigation report for medical devices; and clinical performance evaluation report for IVDMDs	Clinical investigation report	Performance study report
Device registration process	Online registration with CLA Voluntary till Oct 2021 Upload details of the device, ISO 13485 compliance certificate and undertaking Registration No. generated	Basic UDI-DI, (used for traceability of devices) Summary of safety and clinical performance CE number and CE mark	
Comparator device*	Predicate device	Equivalent device	
Essential requirements*	Essential principles	General safety and performance requirements	
Safety database with public access	No database for central reporting of adverse events. No accessibility to public of any safety database	EUDAMED is the central database of EU for medical device. It will be accessible to public from 2022	
Post market clinical evidence	Ways included Vigilance reporting Post marketing clinical investigation PSUR	Ways included PMSR PSUR PMS Postmarketing clinical investigation PMCF CER/PER Clinical evaluation assessment report (prepared by the notified body)	
PSUR structure and frequency*	Structure proposed for PSUR Frequency (for all device class) Every 6 months for first 2 years Annually for subsequent 2 years	No structure proposed for the PSUR Frequency At least annually for Class IIb and Class III devices When necessary and at least every 2 years for Class IIa devices No PSUR for Class I devices	
PSUR requirement*	For all class of devices	For Class IIa, IIb and Class III devices	For Class C and Class D devices

*Similar in IMDR and EU regulations. CER=Clinical evaluation report, CLA=Central Licensing Authority, IVDMD=*In vitro* diagnostic medical device, NA=Not applicable, PER=Performance evaluation report, PMS=Postmarketing surveillance, PMSR=Postmarketing surveillance report, PMCF=Postmarket clinical follow-up, PSUR=Periodic safety update report, UDI-DI=Unique device identification device identifier

WAY FORWARD

India has progressed multi-folds in healthcare and medical devices sectors in the last few years. With the execution of IMDR in 2018, India has paved a new path in the field of medical devices. Today the processes are more transparent, and governments are supporting manufacturers to move forward with more indigenous manufacturing than import. However, when we compare IMDR^[5] to recent EU regulations MDR^[7] and IVDR,^[8] we see a lot of scope for India to tap the untouched areas of governance, transparency, and ease of business accessibility due to regulatory norms.

The IMDR (including amendment 2020) at some instances, provides an incomplete and inconsistent information. For example, if we compare clinical investigation and clinical performance evaluation mentioned in the IMDR; while talking about clinical performance evaluation, IMDR seldom mentions the plan as a clinical investigation plan instead of the clinical performance evaluation plan; the reporting of suspected unexpected serious adverse reaction is mentioned for clinical investigation, but it is not mentioned for clinical performance evaluation; similarly clinical performance evaluation section does not talk about the compensation to the patient in case of death or injury which the clinical investigation section talks about.

Also, when it comes to PMS, IMDR is limited to vigilance reporting, post-marketing clinical investigations, and PSUR (required for all device classes) while EU MDR and IVDR talk about various tools and methods of the PMS system for the manufacturer which includes but is not limited to post-market surveillance report (PMSR, required for class I devices), periodic safety update report (PSUR, required for class IIa, IIb and class III devices), PMS (includes PMS plan and PMSR) and postmarket clinical follow-up studies, vigilance reporting (includes reporting and analysis of serious incidents and field safety corrective actions, trend reporting), post market/market surveillance, post-market clinical investigation, clinical evaluation (CE, includes clinical evaluation plan and clinical evaluation report [CER]) and performance evaluation (includes performance evaluation plan and performance evaluation report [PER]). Clinical Evaluation and Performance Evaluation in EU are not exclusive postmarket requirements, rather they are needed throughout the lifecycle of the device (as mentioned in the clinical evaluation guidelines proposed by the International Medical Device Regulators Forum as well^[13]), i.e., both before and after the marketing of the device; whereas, CE (equivalent process for IVDMs is performance evaluation) in IMDR is required only once

before marketing of the device for design and development validation before granting the manufacturing and/or import licence.

Similarly, medical devices are registered in EU with the help of the CE certificate which is granted only when enough proofs showcase the clinical safety and performance of the device along with the other information. However, in India, devices don't need an elaborate pre-marketing clinical safety data for registration, which leaves a vacuum for an increased number of devices related AE in India.

Moreover, to capture these AEs, there is no central safety database in India which is accessible to public. While EU, on the other hand, has European Databank on Medical Devices (EUDAMED) a section of which will be available to public as well from 2022.^[14]

Like CER and PER, there are a few device evaluations and evaluation reports, mentioned in the EU MDR, that are required throughout the lifecycle of the device, but there is no similar report requirement or procedure to follow in IMDR. Moreover, for the reports that are to be written, the IMDR does not provide the structure for these reports, neither has it given a linkage to any other guidelines for these reports, which creates a gap for the medical device industry in India. However, IMDR proposes a structure of the PSUR which is missing in EU guidelines. In future, CDSCO also needs to cover these aspects of IMDR to give a clearer picture and fulfil the gaps that are existing with the current amendment.^[5,7]

Today many of the devices in India are still defined as drugs as per Drugs and Cosmetics Act 1940, while others are defined under IMDR as devices. In subsequent revisions of the guidelines, the CDSCO may also realign these definitions and put all the medical devices under one common umbrella, making the rules and norms for all these devices similar. This will upturn ease of doing medical device business in India and attract a greater number of manufacturers to invest in India in this segment.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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